EMA/551504/2024
EMEA/H/C/006123

Gohibic (*vilobelimab*)

An overview of Gohibic and why it is authorised in the EU

What is Gohibic and what is it used for?

Gohibic is a medicine used to treat acute respiratory distress syndrome (ARDS) caused by SARS-CoV-2 (the virus that causes COVID-19). ARDS is a condition in which swelling in the lungs causes inflammation and fluid to build up in the air sacs, causing severe difficulty breathing.

Gohibic is used in adults who are being treated with corticosteroid (medicines to reduce inflammation) and mechanical ventilation (breathing assisted by a machine) with or without extracorporeal membrane oxygenation (ECMO, life support that can help a person whose lungs and heart aren't working properly).

Gohibic contains the active substance vilobelimab.

How is Gohibic used?

Gohibic is given as an infusion (drip) into a vein. The first infusion should be given within 48 hours of starting mechanical ventilation (intubation) (day 1 of treatment); subsequent infusions are given on day 2, 4, 8, 15 and 22 of treatment, as long as the patient is hospitalised, even if discharged from the intensive care unit (ICU).

Gohibic can only be obtained with a prescription; treatment should be started and monitored by a doctor experienced in the management of patients treated in an ICU setting.

For more information about using Gohibic, see the package leaflet or contact your doctor or pharmacist.

How does Gohibic work?

The active substance in Gohibic, vilobelimab, is a monoclonal antibody, a type of protein that has been designed to attach to a specific target in the body. Vilobelimab attaches to a protein called C5a, blocking its action. C5a is part of the complement system, a part of the immune system (the body's natural defences). High levels of C5a may cause damage to the lungs, as is seen in patients with severe COVID-19. By blocking the action of C5a, Gohibic helps prevent such damage and allows more oxygen to get into the blood.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

What benefits of Gohibic have been shown in studies?

The benefits of Gohibic were investigated in one main study involving 369 adults with COVID-19; nearly all patients in the study also received treatment with antithrombotics (medicines that reduce the formation of blood clots) and corticosteroids, and all needed mechanical ventilation.

After 28 days of treatment, there were fewer deaths in the group of patients given Gohibic than in the group given placebo (a dummy treatment), both in addition to standard treatment: 32% of patients treated with Gohibic had died, compared with 42% of patients given placebo. However, this difference was not statistically significant, meaning that it could be due to chance.

What are the risks associated with Gohibic?

For the full list of side effects and restrictions with Gohibic, see the package leaflet.

The most common side effects with Gohibic (which may affect more than 1 in 20 people) include infections such as pneumonia (lung infection), herpes simplex infection (viral infection of the mouth (such as cold sores) or the genitals), bronchopulmonary aspergillosis (fungal infection of the lung and airways) and sepsis (when bacteria from an infection elsewhere in the body and their toxins circulate in the blood, leading to organ damage).

Why is Gohibic authorised in the EU?

Although in the main study there were fewer deaths among patients given Gohibic than among those given placebo, this difference was not statistically significant. However, additional analyses and supportive data suggest that there is a reasonable possibility that Gohibic could be of benefit to patients with ARDS due to SARS CoV-2 infection. The safety profile of Gohibic is considered acceptable in a critically ill patient population with limited treatment options. The European Medicines Agency therefore decided that Gohibic's benefits are greater than its risks and it can be authorised for use in the EU.

Gohibic has been authorised under 'exceptional circumstances'. This is because it has not been possible to obtain complete information about Gohibic due to the rarity of the disease, given the declining phase of the COVID-19 pandemic at the time of the medicine's authorisation.

In order to further investigate the efficacy and safety of Gohibic, the company that markets the medicine must submit the results from a further study in patients with moderate to severe ARDS caused by COVID-19 and other viral and bacterial lung infections. The company must also provide yearly updates on any new information concerning the effectiveness and safety of Gohibic.

What measures are being taken to ensure the safe and effective use of Gohibic?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Gohibic have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Gohibic are continuously monitored. Suspected side effects reported with Gohibic are carefully evaluated and any necessary action taken to protect patients.

Other information about Gohibic

Gohibic received a marketing authorisation under exceptional circumstances valid throughout the EU on 13 January 2025.

Further information on Gohibic can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/gohibic

This overview was last updated in 01-2025.